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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/638,151	08/08/2003	Ake Larsson	P03,0282	6077

26574 7590 10/12/2006

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EXAMINER	
MALAMUD, DEBORAH LESLIE	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/638,151	LARSSON, AKE	
	Examiner	Art Unit	
	Deborah Malamud	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 July 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendments received 24 July 2006 are acknowledged. New claims 7-9 are added; claims 1-9 are pending.

Drawings

2. In view of the replacement drawing sheets submitted 24 July 2006, the examiner withdraws the objections to the drawings.

3. However, the drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "signal detector adapted to obtain an electrical signal from the living subject indicative of a degree of stimulation of the vagus nerve of the living subject associated with the stimulation of the phrenic nerve" (lines 6-8 of claim 7) must be shown or the features canceled from the claim. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. In response to the applicant's request for an example of the misspellings of the titles objected to in the previous Non-Final Office Action (dated 13 April 2006), the examiner draws attention to paragraphs 0001 and 003, which appear to have missing letters or inappropriate spacing. The objection is therefore maintained, until these titles and any other errors are corrected.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The stimulation of the vagus nerve is discussed in paragraph

0030 of the specification. No explanation, however, is given there or elsewhere in the specification regarding a structure or method of using a structure that describes "obtaining an electrical signal from the living subject indicative of a degree of stimulation of the vagus nerve" (lines 6-7 of the claim), or "for regulating the pulse generator dependent on the electrical signal to reduce the degree of stimulation of the vagus nerve" (lines 11-12 of the claim). Neither is this structure or method clearly indicated in the original or replacement Figures.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. In view of the amendments to the claims, the examiner withdraws the rejection under 35 103(a) of the previous Non-Final Office Action. New grounds of rejection including the amended subject matter and new claims are discussed below.

9. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al (U.S. 2002/0032468) in view of Zarychta (U.S. 6,411,843). Regarding claims 1, 4-5 and 9, Hill discloses (par. 0077) a stimulation system (200) that includes a breathing regulator (240) that "may be used to stimulate the phrenic nerve in order to provide a diaphragmatic pacemaker. Breathing regulator may comprise one or more electrodes for supplying electrical current to the phrenic nerve to control breathing during vagal and/or cardiac stimulation and/or destimulation." The phrenic nerve stimulation electrodes may include many different types of electrodes, including (par. 0078)

esophageal electrodes. The system (par. 0084) may also include "sensing electrodes (270) to monitor one or more sites of stimulation. Sensing electrodes may be the same electrodes used for nerve stimulation, cardiac stimulation or pain relieving and/or they may be positioned adjacent one or more of the sites of stimulation described above." The examiner considers this to be a pulse generator (nerve stimulator 210), an electrode arrangement connected to the pulse generator and adapted to interact with a living subject to deliver the stimulation pulses to stimulate the vagus nerve, and an esophageal electrode adapted for insertion in the esophagus of the living subject for obtaining measurement signals. The system (par. 0085) may also "include controller (230). Controller may be used to gather information from nerve stimulator and cardiac stimulator. Controller may also be used to control the stimulation levels and stimulation duration of nerve stimulator and cardiac stimulator. Controller may also gather and process information from the various components of system, in particular sensing electrodes. This information may be used to adjust stimulation levels and stimulation times of nerve stimulator, cardiac stimulator, breathing regulator and/or pain relieving electrodes. This adjustment may be based, for example, on data received from monitoring electrodes." The examiner considers this to be a regulating unit connected to the pulse generator for regulating the pulse generator based on the physiological sensor, by varying the shape and energy content of the stimulation pulses. Hill discloses the claimed invention except for a signal analyzer connected to the esophageal electrode for filtering myoelectrical signals originating from the diaphragm of the living subject out of the measurement signals. Zarychta however discloses, (col. 2,

lines 32-35) "producing a model EMG signal from a measured EMG signal that includes a patient's EMG signal and an ECG signal." To measure this EMG signal (col. 6, lines 20-26) "electrodes (12a and 12b) are preferably positioned in esophagus with one electrode (12a) placed very close to diaphragm and the other electrode (12b) placed away from the diagram. Electrodes are connected to an EMG signal processing system (14) disposed outside patient." Zarychta and Hill both disclose systems for stimulating the thoracic region in order to treat a cardiorespiratory condition. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hill's undisclosed physiological sensor with Zarychta's EMG signal analyzer in order to provide immediate feedback on the effect of the electrical neurostimulation on the muscles of the patient for future diagnosis and treatments.

10. Regarding claims 2-3 and 8 and further regarding claim 9, Zarychta discloses (col. 2, lines 27-30) "in the case of a diaphragm EMG signal, the model diaphragm EMG signal can be utilized, for example, to synchronize the operation of a ventilator and the breathing cycles of a patient." Zarychta further discloses (col. 7, lines 10-20) "EMG signal processing system (14) receives measured EMG signal (17) from electrodes (12a,12b and/or 16a, 16b), generates, and supplies to ventilator (18) an amplified model diaphragm EMG signal (19) that corresponds to the diaphragm EMG signal received at diaphragm (10). In a preferred embodiment of the present invention, the amplified model diaphragm EMG signal is used to synchronize the operation of ventilator with the patient's breathing cycle so that the application of an inspiratory pressure or flow by the ventilator is synchronized with the inspiratory effort of the patient, and likewise, the

patient's expiration is synchronized to the expiratory cycle of the ventilator." The examiner considers this ventilator to be a monitoring unit adapted to interact with the living subject for monitoring breathing and generates a monitoring unit output supplied to the regulating unit.

11. Regarding claim 6, Hill discloses, (par. 0080) "the breathing regulator may comprise a connector that interfaces with a patient's respirator, and sends a logic signal to activate or deactivate the respirator to control breathing during vagal and/or cardiac stimulation and/or destimulation." The examiner considers this to be an output interface comprising a plurality of channels. Hill further discloses, (par. 0062; Figure 4) "tube (100) comprising at least two electrodes may be used in a bipolar fashion without the use of one or more external electrodes. For example, tube may be used without the use of collar (101) or external electrode (102). Tube comprising one or more electrodes may be used in a monopolar fashion with the use of one or more external electrodes, for example collar or external electrode. In addition, electrodes of devices (10A, 10B and 10C), for example, may comprise any means capable of forming electrical contact with, for example, nerve stimulator, such as connecting plugs, alligator clips or insulated wires with bared ends." The examiner considers this to be a plurality of electrode leads that are fully capable of being connected to the output interface. The regulating unit is therefore naturally capable of regulating the pulse generator to individually control delivery of stimulation pulses via the respective electrode leads.

12. Regarding claim 7, Hill discloses, (par. 0045) "nerve stimulator (210) may be configured to synchronize activation and deactivation of breathing regulator with vagal

stimulation, thereby minimizing or eliminating unwanted heart and chest motion associated with the patient's breathing." The examiner considers this to be a signal detector adapted to obtain an electrical signal from the living subject indicative of the degree of stimulation of the vagus nerve, wherein the regulating unit regulates the pulse generator dependent on the electrical signal to reduce the degree of stimulation of the vagus nerve.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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